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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,091	04/13/2004	Kirk George Voelker		3090

7590 01/11/2008

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EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
01/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/709,091	VOELKER, KIRK GEORGE	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner notes the receipt of the preliminary amendment dated 4/27/2004. Claims 1-9 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5-6, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bachynsky (U.S. 4,555,397) in view of Kanios et al. (U.S. 5,719,197) and Tanaka et al. (U.S. 3,696110) and further in view of Cary (US 2001/0014678).

Bachynsky teach a method for anticholinergic blockage of withdrawal symptoms in smoking cessation administering a composition containing 0.1-0.8 mg of atropine, 0.2-0.4 mg scopolamine and from about 10.0 - 50.0 mg chlorpromazine in a suitable carrier (col. 1, claim 1). The reference teach that anticholinergic drugs act predominantly at muscarinic sites in the cerebral cortex and following the initial office visit and

treatment, the patient may be placed upon oral doses of predominantly centrally acting anti-cholinergic drugs for a period of up to two weeks or longer (col. 2, lines 30-39). The reference also teach the use of scopolamine patches as a follow up treatment (col. 4, line 6).

The reference does not teach hyoscyamine in the anticholinergic medication in a method of minimizing nicotine withdrawal symptoms.

Kanios et al. teach atropine and hyoscyamine are anticholinergics (col. 17, lines 66-67, col. 18, lines 2 and 18).

Tanaka et al. teach atropine and hyoscyamine are optical isomers (See Abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have added hyoscyamine in the anticholinergic medication in a method of minimizing nicotine withdrawal symptoms because Tanaka et al. teach atropine and hyoscyamine as optical isomers, Kanios et al. teach atropine and hyoscyamine as anticholinergics and Bachynsky teach a method of minimizing the physical withdrawal symptoms by administering anticholinergic compounds and exemplify atropine as one of the compounds in the composition. A person of ordinary skill in the art would have been motivated to formulate a composition with hyoscyamine in the anticholinergic medication in a method of minimizing nicotine withdrawal symptoms because of expectation of success and in achieving similar or better therapeutic benefits in substituting one anticholinergic for another. One of ordinary skill in the art would have been motivated in expectation of synergistic and or additive effects in adding an

anticholinergic agent such as hyoscyamine to a composition consisting scopolamine (anticholinergic agent) in the anticholinergic medication in a method of minimizing nicotine withdrawal symptoms.

The references do not teach hydroxyzine in the anticholinergic medication in a method of minimizing nicotine withdrawal symptoms.

Cary teach methods of treating patients for tobacco addiction and nicotine addiction for palliating the effects of nicotine withdrawal comprising administering antidepressant or an anti-anxiety compounds (see Abstract). Cary teach that anxiolytics have also been administered to treat nicotine withdrawal to counter the mild anxiety symptoms that occur during smoking cessation treatment (para 0013, lines 1-3). The reference teach that buspirone, an anti-anxiety drug can be used in combination with a nicotine receptor antagonist. The reference also teach that hydroxyzine (anti anxiety drug) can also be used (para 0027). The reference teach that antidepressants have oftentimes been used to treat symptoms of nicotine withdrawal and exemplify bupropion (p 1, para 0011, lines 1-3). Cary teach that for oral administrations, the pharmaceutical composition disclosed may take the form of a tablet or capsules (para 0054). The reference teach an amount of 5-10 mg of buspirone, an anxiolytic in a formulation (example 8) in a method to treat tobacco or nicotine addiction.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have added hydroxyzine in the anticholinergic medication in a method of minimizing nicotine withdrawal symptoms because Cary teach that anxiolytics have also been administered to treat nicotine withdrawal to counter the mild anxiety symptoms

that occur during smoking cessation treatment and further teach hydroxyzine as one of the anti anxiety drug. A person of ordinary skill in the art would have been motivated to formulate a composition with hydroxyzine in the anticholinergic medication in a method of minimizing nicotine withdrawal symptoms because of expectation of success and to counter the mild anxiety symptoms that occur during smoking cessation treatment. The references do not teach an amount of hydroxyzine in the anticholinergic medication in a method of minimizing nicotine withdrawal symptoms. Cary teach an amount of 5-10 mg of buspirone, an anxiolytic in a formulation in a method to treat tobacco or nicotine addiction. It would have been obvious to one of ordinary skill in the art to use similar amounts of hydroxyzine in the formulation in expectation of similar therapeutic benefits. The amount of an ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bachynsky (U.S. 4,555,397) in view of Kanios et al. (U.S. 5,719,197) and Tanaka et al. (U.S. 3,696110) and further in view of Cary (US 2001/0014678) as applied to claims 1-

3, 5-6, 9 above and further in view of Siebert et al. (US 2005/0107349, effective filing date, July 24 2003).

Bachynsky, Kanios et al., Tanaka et al and Cary's teachings discussed as above.

The references do not teach glycopyrrolate in the anticholinergic medication in a method of minimizing nicotine withdrawal symptoms.

Siebert et al. teach scopolamine, glycopyrrolate and atropine as muscarinic receptor (anticholinergic) antagonists (para 1237). The reference further teaches an amount of muscarinic receptor antagonist to be in the range from about 0.01 mg to 5000 mg (para 1270, 1311).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have added glycopyrrolate in the anticholinergic medication in a method of minimizing nicotine withdrawal symptoms because Siebert et al. teach scopolamine, glycopyrrolate and atropine sulfate are all anticholinergic agents. Bachynsky teach a method of minimizing the physical withdrawal symptoms by administering anticholinergic compounds and exemplify scopolomine as one of the compounds in the composition A person of ordinary skill in the art would have been motivated to formulate a composition with glycopyrrolate in the anticholinergic medication in a method of minimizing nicotine withdrawal symptoms because of expectation of success and in achieving similar or better therapeutic benefits in substituting one anticholinergic for another. One of ordinary skill in the art would have been motivated in expectation of synergistic and or additive effects in adding an anticholinergic agent such as glycopyrrolate to a composition consisting scopolamine (anticholinergic agent) and

hydroxyzine in the anticholinergic medication in a method of minimizing nicotine withdrawal symptoms.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bachynsky (U.S. 4,555,397) in view of Kanios et al. (U.S. 5,719,197) and Tanaka et al. (U.S. 3,696110) and further in view of Cary (US 2001/0014678) as applied to claims 1-3, 5-6, 9 above and further in view of Siebert et al. (US 2005/0107349, effective filing date, July 24 2003) as applied to claim 4 and further in view of Hudson (U.S. 6,132,754).

Bachynsky, Kanios et al., Tanaka et al, Cary's and Siebert et al. teachings discussed as above.

The references do not teach a behavioral modification program or counseling as an adjunct therapy to anticholinergic medication.

Hudson teach a method of helping a patient eliminate tobacco dependency by combining medications and behavioral therapy (see Abstract). The reference teach that numerous methods to eliminate tobacco dependency have been used including hypnotism, psychotherapy, group counseling etc (col. 2, lines 7-10). The reference that specific compounds of anticholinergic medications given parenterally provide the initial blockade of nicotine receptor sites, thus providing immediate relief to the nicotine withdrawal syndrome and oral anticholinergics and scopolamine patches sustain low levels of anticholinergic and blocking affinity of nicotine receptor sites (col. 2, lines 66-67, col. 3, lines 1-10). The reference also teach benzodiazepines are preferred in smoking cessation for the ability to reduce anxiety levels, hypnotic qualities and short

half life (col. 3, lines 14-17). The reference teach that implementation of behavioral therapy designed specifically for nicotine addiction allows the patient to experience physical and emotional pleasure during the cessation period and the brain experiences cessation and pleasure as one collective experience and allows change to occur naturally (col. 3, lines 21-25).

It would have been obvious to one of ordinary skill in the art to implement a behavioral modification therapy or counseling as an adjunct therapy to anticholinergic medication from the teachings of Hudson. Hudson teach combination therapy of medications including anticholinergics along with behavioral therapy. One having ordinary skill in the art would have been motivated to implement a behavioral modification therapy or counseling as an adjunct therapy to anticholinergic medication because implementation of behavioral therapy designed specifically for nicotine addiction will allow the patient to experience physical and emotional pleasure during the cessation period as taught by Hudson.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER